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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,441	02/22/2005	Rebecca H. Li	08702.0110-00000	3832

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,441	LI ET AL.	
	Examiner	Art Unit	
	ABDEL A. MOHAMED	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,74-79,81-83,85,92,96-99,101-103,105,107 and 113-116* is/are pending in the application.

4a) Of the above claim(s) *76-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72,74,75,81-83,85,92,96-99,101-103,105,107 and 113-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO remains the same. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Abdel A. Mohamed.

ACKNOWLEDGMENT TO PRIORITY, AMENDMENT, REMARKS, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application is filed under 35 U.S.C. 371 on 02/22/05 having a filing date of 05/12/03 of PCT/US03/14609. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The amendment, remarks and information disclosure statement filed 06/11/08 are acknowledged, entered and considered. In view of Applicant's request claims 85, 97, 98, 105, 113 and 115 have been amended and claims 119 and 120 have been canceled. Claims 72, , 74-79, 81-83, 85, 92, 96-99, 101-103, 105, 107 and 113-116 are now pending in the application of which claims 76-79 are withdrawn as non-elected invention and claims 72, 74, 75, 81-83, 85, 92, 96-99, 101-103, 105, 107 and 113-116 are currently examined as *per* elected invention. The rejections under 35 U.S.C. 112, second paragraph, 35 U.S.C. 102(b)/103(a), 35 U.S.C. 101 double patenting and 35 U.S.C. obviousness- type double patenting are withdrawn in view of Applicant's amendment and remarks filed 06/11/08. However, the rejection under 35 U.S.C. 103(a) over the prior art of record has been maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2 Claims 72, 74, 75, 81-83, 85, 96-99, 101-103, 105, 107, and 113-116 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al., (WO 01/28602 A1) (provided by Applicants) in view of Vercruysee et al, Hyaluronate Derivatives in Drug Delivery, Critical Review in Therapeutic Drug Carrier Systems, 1998, 15(5), 513-555 and Campoccia et al, Semisythetic resorbable materials from hyaluronan

esterification, Biomaterials, 1998, 19, 2101-2127 (provided by Applicants) and further in view of Shalaby, et al. (US 6,221,958) and Daifotis et al (US 6,015,801).

Applicant's arguments filed 06/11/08 have been fully considered but they are not persuasive. Applicant has argued that the primary reference of WO 01/28602 (Kim) does not teach or suggest that its compositions are in the form of a solid cylindrical rod before injection or that they would be in rod shape even after injection. Further, none of the secondary references cited by the Examiner, alone or in combination remedy the deficiencies of the primary reference of Kim. Their collective disclosures fail to offer any teaching, suggestion, or motivation to make the composition of the primary reference of Kim in the form of a solid cylindrical rod suitable for intraosseous injection. Consequently, none of these references, alone or in combination, render the instant claims obvious is unpersuasive.

Contrary to Applicant's arguments as discussed in the previous Office action and reiterated here, the primary reference of Kim discloses an injectable, including intraosseous injections, formulation comprising a pharmaceutically acceptable admixture of an osteogenic protein, hyaluronic acid derivatives and tricalcium phosphate and formulating porous injectable gels and pastes (See e.g., abstract, pg. 1, lines 4-8, pg. 2, lines 13-15, pg. 3, lines 7-9). Kim additionally discloses that the injectable formulation of the invention allows for closed fracture repair and other skeletal tissue without an open reduction procedure as is necessary with implantable devices and that the methods for preparing injectable gels or pastes useful as a carrier for osteogenic protein are made by transforming various non-woven pads and sponges of

hyaluronic acid benzyl ester into injectable gel or paste formulations by hydration or solvent addition yielding gels with in vivo residence times from days to up to several months, which can be used to promote the formation of cartilage and/or bone, for repair of tissue damage and fractures, cartilage and/or bone repair and/or growth (See e.g., pg. 2, lines 15-27, pg. 3, lines 7-12). Kim further discloses that the preferred osteogenic proteins for use are those of the BMP class identified as BMP-1 through BMP-12, with the most preferred being BMP-2. Kim states that injectable formulations may also find application to other bone sites such as bone cysts, bone defects, intraosseous sites and closed fractures, and that formulations may be used as a substitute for antilogous bone graft in fresh and non-union fractures; spinal fusions; bone defect repair in the orthopedic field; cranio/maxillofacial reconstructions; prosthesis integration, especially as a surface coating to improve fixation of prosthetic implants; in osteomyelitis for bone regeneration; in the dental field for augmentation of the alveolar ridge and periodontal defects and tooth extraction sockets; in the treatment and/or prevention of osteoporosis, or the treatment of osteoporotice or osteopenic bone. Kim then discusses the addition of other components to the osteogenic protein/hyaluronic acid benzyl ester composition based upon conditions to be treated, i.e. with osteomyelitis antibiotics may be added and other drugs, growth factors, peptides, proteins, cytokines, oligonucleotides, antisense oligonucleotides, DNA and polymers may be added (See e.g., pgs. 4-5, lines 16-25). Kim then discloses the preparation of injectable hyaluronic acid esters using Hyaff11, Hyaff11p80 and Hyaff11p65 using organic solvents (Hyaff11 and Hyaff11p80) and aqueous buffers (Hyaff11p65) to which rhBMP-2 was added. The in vitro release

kinetics, rat ectopic assay, and in vivo biodistribution were evaluated (See e.g., pgs 6-11).

The Examiner acknowledges that the primary reference of Kim does not explicitly teach that the composition is in the form of a cylindrical rod. Additionally, Kim does not teach that the hyaluronic acid ester is a cross-linked hyaluronic acid, the specific diameters and lengths of the cylindrical rod, forming and drying the osteogenic mixture into a cylindrical rod, extruding the osteogenic mixture, whether in a nonsolvent (ethanol or water) or into the air, and drying and the addition of bisphosphonate compounds for inhibiting bone resorption in patients with osteoporosis.

However, the secondary reference of Vercruysee discloses that sodium hyaluroate and hyaluronic acid are collectively determined as hyaluronan, abbreviated as HA (See e.g., pg. 514, first paragraph). Vercruysee additionally discloses that unmodified HA has found important applications in drug delivery and surgery and that the physiochemical properties of HA can be adapted to the desired application by chemical modification and furthermore it can be gathered that HA-drug hydrogels (would include HA ester derivatives for drug delivery) may be used to localize a slow release formulation at a specific site in the body (See e.g., pgs. 514-516). Vercruysee further discloses the production and possible used of chemically modified hyaluronic acids for drug delivery and in the Table shown on page 516 specifies derivatives of HA as, e.g., HA ester derivatives for the use in drug delivery and their availability from co-patentee Fidia (Advanced Biopolymers S.R.L.) and presents an overview of the in vitro and in vivo release studies performed with these material (See e.g., pgs. 515-516, 528-

534, 537-539). Vercuysee discloses on page 519 the esterification of the carboxylic acid groups of HA and in Table 2 on page 533 HYAFF11px (px refers to the percentage of carboxylic function modified) Hyaff11, which is one of the preferred compound of the instant application and used in the Examples is discussed as well as Hyaff11p50, and Hyaff11p75 throughout the article.

Further, the secondary reference of Campoccia discloses hyaluronic Acid and partially or completely esterified forms of hyaluronic acid, wherein ester formation and the properties of the obtained hyaluronic acid ester are described (See e.g., entire article, especially pg. 2103). Campoccia discloses that cross-linking was a way to obtain a modified stable form of HA, that new classes of insoluble polymers were developed using a variety of cross-linking agents to trap HA chains within a net of cross-linked proteins or to create covalent bonds between HA chains and that the list of cross-linked derivatives is even longer and includes esterified HA chains (See e.g., pg. 2103). Additionally, Campoccia discloses that the vast majority of the described cross-linked materials are water insoluble gels with better viscosity and chemical stability that HA, and are generally susceptible to extensive hydration in aqueous solution as disclosed on page 2103. Also on page 2103, Campoccia discloses that Hyaff11 is one of the most characterized Hyaff polymers from both the physiochemical and biological view points and is useful in understanding the effect that changing two variables, the type of ester and the percentage of esterification have on molecular properties, i.e. the extent of molecular modification modulates the soluble and viscous nature of the purified hyaluronan in aqueous solution and has proved to have profound effects on the inter

action of hyaluronan with water (the higher percentage of esterification of hyaluronan, the lower its solubility in water; the total benzyl ester Hyaff11 sowed only slight hydration when placed in buffered phosphate saline solution and 75% hyaluronan benzyl esters, Hyaff1p75, hydration was even greater). Furthermore, Campoccia discloses the degradation profiles between Hyaff11 (slower degradation, 2-3 months, more stable) and hydrated Hyaff11p75 (1-2 weeks) probably because partial esters are more flexible than more complete esterified ester in which the hydrophobic patches make the polymer chain network more rigid and stable (See e.g., pgs. 2105 and 2112-2113). Campoccia further discloses that once esterification of the polymer has been obtained, the material can easily be processed to produce membranes, fibers, sponges, microcopies and other devices by extrusion, lyophilization or spray drying (See e.g., pg. 2103). Moreover Campoccia discloses the use of hyaluronan esters for drug delivery purposes or as a carrier (See e.g., pgs. 2113-2114). Campoccia concludes that it is clear that hyaluronan derivatives have considerable potential as biomaterials because the may be prepared with varying degrees of stability, ranging from readily water-soluble to solid polymers with in vivo lifetimes measured in months and are cytocompatible polymer (See e.g., pgs. 2120-2123).

Furthermore, the secondary reference of Shalaby discloses sustained release formulations of proteins/peptides made from pastes and extruded from 18 gauge needles (close to 16 gauge and would have a diameter within 0.5 to 1.5 mm) to form rods and cut into lengths that had the proper dosage of drug and placed into a sterile 10 gauge needle (ready for injection) See e.g., cols. 4-5, lines 52-5, col. 6, lines 10- 17, col.

14, lines 47-61, Example C-1 (col. 20), Example C-3 (col. 21), Example C-4 (col. 22), Claims 1, 5, 19, 20, 21, 28, 29, 30). Shalaby does not explicitly disclose that the rods are dried. However, drying is implied as they are extruded and then loaded into a different gauge syringe and it would be difficult if not impossible to reload the rods without letting them harden.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to create a composition for injectable delivery of BMP-2 comprising BMP-2 and Hyaff11 (100% esterification) or Hyaff11p65 (65% esterification), wherein the composition is in the form of a cylindrical rod suitable for intraosseous injection in solid state into a body, where the diameter of the rod is between 0.5 and 1.5 mm with a reasonable expectation of success because the prior art suggests that HA benzyl ester derivatives are biodegradable, are intrinsically safe to use, can be used in sustained-release/drug delivery systems, can be extruded and are chosen based upon various physico-chemical properties, including viscosity, bioavailability, and degradation and that a preferred form of sustained release peptides in paste are extruded into rods and implanted and the matrix would not change the method. Additionally, the formation of rods through extrusion has the added benefits of being cheap and easily used decreasing the risks of implants that are associated with any type of surgery.

Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to create a composition for injectable delivery of BMP-2 comprising BMP-2 and Hyaff11 (100% esterification) or Hyaff11p65 (65% esterification), wherein the composition is in the form of a cylindrical rod suitable for intraosseous injection in solid

state into a body, where the diameter of the rod is between 0.5 and 1.5 mm and the length is between about 2 cm to 5 cm with a reasonable expectation of success because the prior art suggests that HA benzyl ester derivatives are biodegradable, are intrinsically safe to use, can be used in sustained-release/drug delivery systems, can be extruded and are chosen based upon various physico-chemical properties, including viscosity, bioavailability, and degradation and the length will be determined by comfort, needle length, dosage of the drug, all of which a skilled artisan would utilize in conjunction with the age of the patient, the severity of the illness, the weight of the patient, etc. to obtain optimal dosing and that a preferred form of sustained release peptides in paste are extruded into rods and implanted and the matrix would not change the method. Additionally, the formation of rods through extrusion has the added benefits of being cheap and easily used decreasing the risks of implants that are associated with any type of surgery.

Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to make a composition for treating osteoporotic bone comprising mixing BMP-2 and Hyaff11 or Hyaff11p65 to form an osteogenic mixture by hydration or solubilization of insoluble or partially soluble particles, films, fibers, non-woven pads, or sponges of Hyaff11 or Hyafflp65 in the presence of an organic solvent or aqueous buffer and forming by extrusion into the air and drying the mixture into a cylindrical rod suitable for intraosseous injection in solid state into a body with a reasonable expectation of success because the prior art suggests that HA benzyl ester derivatives are biodegradable, are intrinsically safe to use, can be used in sustained-release/drug

delivery systems, can be extruded and are chosen based upon various physico-chemical properties, including viscosity, bioavailability, and degradation and that a preferred form of sustained release peptides in paste are extruded into rods and implanted and the matrix would not change the method. Additionally, the formation of rods through extrusion has the added benefits of being cheap and easily used decreasing the risks of implants that are associated with any type of surgery.

Additionally it would have been obvious to one of ordinary skill in the art at the time of the invention to make a composition for treating osteoporotic bone comprising mixing BMP-2 and Hyaff11 or Hyaff11p65 to form an osteogenic mixture by hydration or solubilization of insoluble or partially soluble particles, films, fibers, non-woven pads, or sponges of Hyaff11 or Hyafflp65 in the presence of an organic solvent or aqueous buffer and forming by extrusion into a nonsolvent, such as water or ethanol, and drying the mixture into a cylindrical rod suitable for intraosseous injection in solid state into a body with a reasonable expectation of success because the prior art suggests that HA benzyl ester derivatives are biodegradable, are intrinsically safe to use, can be used in sustained-release/drug delivery systems, can be extruded and are chosen based upon various physico-chemical properties, including viscosity, bioavailability, and degradation; that a preferred form of sustained release peptides in paste are extruded into rods and implanted and the matrix would not change the method; and that extruding the mixture into a nonsolvent would permit the extrusion to remove any impurities that are soluble and/or would ease the flow of the paste through the syringe. Additionally, the formation of rods through extrusion has the added benefits of being cheap and

easily used decreasing the risks of implants that are associated with any type of surgery.

Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to create a composition for injectable delivery of BMP-2 comprising BMP-2 and Hyaff11 (100% esterification/crosslinked) or Hyaff11p65 (65% esterification/crosslinked), wherein the composition is in the form of a cylindrical rod suitable for intraosseous injection in solid state into a body, where the diameter of the rod is between 0.5 and 1.5 mm and the length is between about 2 cm to 5 cm with a reasonable expectation of success because the prior art suggests that HA benzyl ester derivatives are biodegradable, are intrinsically safe to use, can be used in sustained-release/drug delivery systems, can be extruded and are chosen based upon various physico-chemical properties, including viscosity, bioavailability, and degradation and the length will be determined by comfort, needle length, dosage of the drug, all of which a skilled artisan would utilize in conjunction with the age of the patient, the severity of the illness, the weight of the patient, etc. to obtain optimal dosing; that a preferred form of sustained release peptides in paste are extruded into rods and implanted and the matrix would not change the method and to improve the stability of the HA and HA derivatives and would exclude the leaching of any toxic cross-linking agents which may be used to bridge polymer chains as taught by the secondary reference of Campoccia and thus improve the stability and safety of the matrix. Additionally, the formation of rods through extrusion has the added benefits of being cheap and easily used decreasing the risks of implants that are associated with any type of surgery.

With respect to the addition of alendronate, a bisphosphonate compound for inhibiting bone resorption in patients with osteoporosis, the secondary reference of Daifotis discloses that despite their therapeutic benefits, bisphosphonates (which would include alendronate) are poorly absorbed from the gastrointestinal tract and that intravenous administration has been used to overcome this bioavailability problem but that i.v. administration is costly and inconvenient, especially when the patient must be given an intravenous infusion lasting several hours on repeated occasions (See e.g., col. 1, lines 55-60). On col. 2, lines 4-16, Daifotis also discloses that when oral administration of the bisphosphonate is desired relatively high does must be administered to compensate for the low bioavailability from the gastrointestinal tract and that oral administration has been associated with adverse gastrointestinal effects, especially those relating to the esophagus.

Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to have added alendronate to the BMP-2/Hyaff11 or Hyaff11p65 matrix with a reasonable expectation of success because the prior art suggests that other drugs can be added to the matrix without any adverse effects, that the composition is useful to treat osteoporosis fractures, that alendronate will be utilized if it reaches the blood stream and that if alendronate is included in the matrix, the problems associated with oral and intravenous methods of administration will be alleviated, i.e. one would have increased availability of the drug, lower costs, better compliance and increase convenience.

In regard to claims 99 and claims dependent thereof (i.e., claims 101-103, 105, 107 and 113-116), the claims are in product-by-process format and as such, it is the novelty and patentability of the instantly claimed product that need be established and not the recited process steps, *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976). Further, the prior art described the product as old, *In re Best,* 195 USPQ 430, 433 (CCPA 1977); (See MPEP 706.03[e]). Hence, the burden of proving that the process limitation makes a different product is shifted to the Applicant, *In re Fitzgerald*, 205 USPQ 594.

Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would be able to formulate a composition in the form of a cylindrical rod suitable for intraosseous injection in solid state into a body. Because, the same preferred hyaluronic acid esters (Hyaff-11 or Hyaff -11p65), the same bisphosphonate and several of the same BMPs, and the same solubilizing organic solvents are explicitly recited as being parts of the composition. Thus, for one of ordinary skill in the art, this is an obvious variation because it would involve nothing more than an arbitrary matter of experimental design choice to select the appropriate form over another. Such a choice is within the skill of the ordinary artisan of bone repairs. Further, “a cylindrical rod” is a form of material that would not change the composition. For example, sugar can be in a form of granular, cube or powder, but has the same usage as sweetening agent and does not change the ultimate use. Thus, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art to which this invention pertains at the time the invention was made, as evidenced by the combined

teachings of the references, which fall with the scope of the prior art injectable or implantable solid pharmaceutical formulations comprising hyaluronic acid derivatives and osteogenic proteins would have been obvious because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them".

OBJECTION TO TRADEMARKS AND THEIR USE

3. The use of the trademarks "Hyaff-11®", "Hyaff-11p65®", "Teflon®/FEP", "Hyaff-11p80®", "Hyaff®", "Calasept®", "Henke-Ject®", "Hypo®" and "Luer-Lok®" have been noted in this application. The trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology. Although, the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner, which might adversely affect their validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirements are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

ACTION IS FINAL

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABDEL A. MOHAMED whose telephone number is (571)272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657